Precis: Phase II clinical trial of rv-PSA + rv-B7.1 with GM-CSF and IL-2 followed by sequential vaccination with rF-PSA and GM-CSF and IL-2 versus antiandrogen therapy with Nilutamide.

This trial will evaluate the efficacy and immunologic effects of a vaccination regimen composed of (1) recombinant vaccinia virus that expresses the Prostate Specific Antigen gene (rV-PSA), (2) recombinant vaccinia virus that expresses B7.1 costimulatory admixture (rV-B7.1), and (3) sequential vaccinations with recombinant fowlpox virus containing the PSA gene (rF-PSA) compared to the efficacy of antiandrogen therapy with Nilutamide in patients with hormone refractory prostate cancer with increasing PSA levels but with no radiographic evidence of metastatic disease. Patients randomized to the vaccine arm will in addition receive GM-CSF and IL-2 as part of their vaccination schedule. Patients will continue therapy monthly until there is radiographic evidence of metastatic disease. The primary endpoint is to identify progression of disease at six months to determine if there is a statistically significant difference in time to progression. At any interval at or after this 6 month time point, patients with a rising PSA without radiographic evidence of disease progression will be offered the option to begin additional therapy with the treatment offered in the other arm. Serum Immunologic markers and PSA levels will be followed as secondary endpoints while patients continue to receive treatment on the protocol. Patients with PSA-expressing adenocarcinoma of the prostate will be evaluated for eligibility that includes a history of prior vaccinia (as vaccine against smallpox) and immunocompetence. (See Schema below).